

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative Martin Moynihan on July 2, 2009.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

In the Claims:

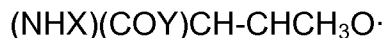
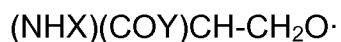
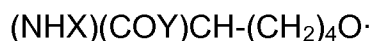
1-113. (Canceled)

114. (Currently Amended) A process of producing a polymer comprising:
 (a) providing hydroxyl-carboxyl protomers; and
 (b) condensing said hydroxyl-carboxyl protomers to form at least one bond A-B, thereby producing the polymer,
 wherein:

A is selected from the group of radicals consisting of:

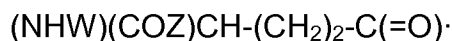


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and $(\text{NHX})(\text{COY})\text{CH}-\text{CH}_2-\text{C}_6\text{H}_4 \text{ p-O}\cdot$,

and

B is selected from the group of radicals consisting of

and $\text{WNHCHR}_B\text{C}(=\text{O})\cdot$ wherein R_B is selected from the group consisting of:

$-(\text{CH}_2)_3-\text{NH}-\text{C}(\text{NH}_2)(=\text{NH})$, $-(\text{CH}_2)_3-\text{NH}-\text{C}(\text{OH})(=\text{NH})$, $-(\text{CH}_2)_4\text{NH}_2$, $-(\text{CH}_2)_4\text{OH}$,

$-\text{CH}_2\text{OH}$, $-\text{CHOHCH}_3$, $-\text{CH}_2-\text{C}_6\text{H}_4 \text{ p-OH}$, $-\text{CH}_2\text{CONH}_2$, $-\text{CH}_2\text{COOH}$, $-(\text{CH}_2)_2\text{CONH}_2$, $-(\text{CH}_2)_2\text{COOH}$, $-\text{CH}_2\text{SH}$, $-\text{H}$, $-\text{CH}_3$, $-\text{CH}_2\text{c}(\text{C}=\text{CH}-\text{N}=\text{CH}-\text{NH}-)$, $-\text{CH}(\text{CH}_3)\text{CH}_2\text{CH}_3$,

$-\text{CH}_2\text{CH}(\text{CH}_3)_2$, $-(\text{CH}_2)_2\text{SCH}_3$, $-\text{CH}_2\text{C}_6\text{H}_5$, $-\text{CH}_2-\text{c}(\text{C}=\text{CH}-\text{NH}-\text{Ph}-)$ and $-\text{CH}(\text{CH}_3)_2$,

wherein Y and Z are independently selected from the group consisting of OH and a proteinaceous material; and

wherein W and X, are independently selected from the group consisting of H and a proteinaceous material; and

wherein bond A-B is an ester bond.

115. (Currently Amended) The process of claim 114, wherein at least one of said hydroxyl-carboxyl protomers has a structure of:



wherein:

Y' is a proteinaceous material, OH or NH_2 ; and

R_a is selected from the group consisting of $-(\text{CH}_2)_3-\text{NH}-\text{C}(\text{NH}_2)(=\text{NH})$,

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$-(\text{CH}_2)_3\text{-NH-C(OH)(=NH)}$, $-(\text{CH}_2)_4\text{NH}_2$, $-(\text{CH}_2)_4\text{OH}$, $-\text{CH}_2\text{OH}$, $-\text{CHOHCH}_3$, $-\text{CH}_2\text{-C}_6\text{H}_4$ p-OH, $-\text{CH}_2\text{CONH}_2$, $-\text{CH}_2\text{COOH}$, $-(\text{CH}_2)_2\text{CONH}_2$, $-(\text{CH}_2)_2\text{COOH}$, $-\text{CH}_2\text{SH}$, $-\text{H}$, $-\text{CH}_3$, $-\text{CH}_2\text{c(C=CH-N=CH-NH-)}$, $-\text{CH(CH}_3\text{)CH}_2\text{CH}_3$, $-\text{CH}_2\text{CH(CH}_3\text{)}_2$, $-(\text{CH}_2)_2\text{SCH}_3$, $-\text{CH}_2\text{C}_6\text{H}_5$, $-\text{CH}_2\text{-c(C=CH-NH-Ph-)}$, and $-\text{CH(CH}_3\text{)}_2$.

116. (Currently Amended) The process of claim 114, wherein at least one of said hydroxyl-carboxyl protomers has a structure



wherein:

n is 0 or a positive integer;

Y_n is a proteinaceous material, OH or NH_2 ; and

R_a , R_c and each one of R_n is independently selected from the group consisting of

$-(\text{CH}_2)_3\text{-NH-C(NH}_2\text{)(=NH)}$, $-(\text{CH}_2)_3\text{-NH-C(OH)(=NH)}$, $-(\text{CH}_2)_4\text{NH}_2$, $-(\text{CH}_2)_4\text{OH}$, $-\text{CH}_2\text{OH}$, $-\text{CHOHCH}_3$, $-\text{CH}_2\text{-C}_6\text{H}_4$ p-OH, $-\text{CH}_2\text{CONH}_2$, $-\text{CH}_2\text{COOH}$, $-(\text{CH}_2)_2\text{CONH}_2$, $-(\text{CH}_2)_2\text{COOH}$, $-\text{CH}_2\text{SH}$, $-\text{H}$, $-\text{CH}_3$, $-\text{CH}_2\text{c(C=CH-N=CH-NH-)}$, $-\text{CH(CH}_3\text{)CH}_2\text{CH}_3$, $-\text{CH}_2\text{CH(CH}_3\text{)}_2$, $-(\text{CH}_2)_2\text{SCH}_3$, $-\text{CH}_2\text{C}_6\text{H}_5$, $-\text{CH}_2\text{-c(C=CH-NH-Ph-)}$, and $-\text{CH(CH}_3\text{)}_2$.

117. (Original) The process of claim 114, wherein said providing said hydroxyl-carboxyl protomers comprises:

- (i) providing a protein-containing substrate; and either or both
 - (ii) replacing primary amines of proteinaceous components of said protein-containing substrate with hydroxyl groups; and / or
 - (iii) replacing amide groups of proteinaceous components of said protein-containing substrate with carboxyl groups;
- so as to make said protomers from said proteinaceous components.

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118. (Original) The process of claim 117, wherein said providing said hydroxyl-carboxyl protomers comprises:

- (i) providing a protein-containing substrate; and
 - (ii) replacing primary amines of proteinaceous components of said protein-containing substrate with hydroxyl groups;
- so as to make said protomers from said proteinaceous components.

119. (Original) The process of claim 117, wherein said providing said hydroxyl-carboxyl protomers comprises:

- (i) providing a protein-containing substrate; and
 - (ii) replacing amide groups of proteinaceous components of said protein-containing substrate with carboxyl groups;
- so as to make said protomers from said proteinaceous components.

120. (Original) The process of claim 117, wherein prior to said replacing, proteinaceous compounds in said protein containing substrate are hydrolyzed.

121. (Original) The process of claim 117, wherein said replacing comprises reacting said proteinaceous compounds with nitrous acid or nitrous oxides.

122. (Original) The process of claim 114, wherein said reacting takes place in an aqueous reaction solution, the pH of said aqueous reaction solution is adjusted by the addition of at least one compound, said at least one compound being selected from the group consisting of amine, carboxylic acid and a conjugate base of a carboxylic acid.

123. (Currently Amended) A process of producing a polymer comprising:

- (a) providing hydroxyl-carboxyl protomers;
- (b) providing at least one copolymer;

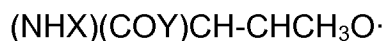
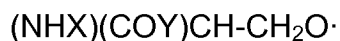
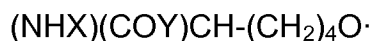
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(c) combining said hydroxyl-carboxyl protomers with said at least one copolymer to make a precursor mix; and

(d) condensing molecules in said precursor mix to form the polymer, said condensing comprising forming at least one bond A-B,

wherein:

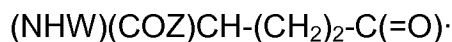
A is selected from the group of radicals consisting of:



and $(\text{NHX})(\text{COY})\text{CH}-\text{CH}_2-\text{C}_6\text{H}_4 \text{ p-O}\cdot$,

and

B is selected from the group of radicals consisting of



and $\text{WNHCHR}_B\text{C}(=\text{O})\cdot$

wherein R_B is selected from the group consisting of:

$-(\text{CH}_2)_3-\text{NH}-\text{C}(\text{NH}_2)(=\text{NH})$, $-(\text{CH}_2)_3-\text{NH}-\text{C}(\text{OH})(=\text{NH})$, $-(\text{CH}_2)_4\text{NH}_2$, $-(\text{CH}_2)_4\text{OH}$,

$-\text{CH}_2\text{OH}$, $-\text{CHOHCH}_3$, $-\text{CH}_2-\text{C}_6\text{H}_4 \text{ p-OH}$, $-\text{CH}_2\text{CONH}_2$, $-\text{CH}_2\text{COOH}$, $-(\text{CH}_2)_2\text{CONH}_2$, $-(\text{CH}_2)_2\text{COOH}$, $-\text{CH}_2\text{SH}$, $-\text{H}$, $-\text{CH}_3$, $-\text{CH}_2\text{C}(\text{C}=\text{CH}-\text{N}=\text{CH}-\text{NH}-)$, $-\text{CH}(\text{CH}_3)\text{CH}_2\text{CH}_3$,

$-\text{CH}_2\text{CH}(\text{CH}_3)_2$, $-(\text{CH}_2)_2\text{SCH}_3$, $-\text{CH}_2\text{C}_6\text{H}_5$, $-\text{CH}_2-\text{c}(\text{C}=\text{CH}-\text{NH}-\text{Ph}-)$ and $-\text{CH}(\text{CH}_3)_2$,

wherein Y and Z are independently selected from the group consisting of OH and a proteinaceous material; and

wherein W and X, are independently selected from the group consisting of H and a proteinaceous material; and

wherein bond A-B is an ester bond.

124. (Original) The process of claim 123, wherein said condensing is reaction of a hydroxyl group of a first protomer with a carboxyl group of a second protomer so as to form an inter-protomer ester bond.

125. (Original) The process of claim 123, wherein said condensing is bond-forming reaction of a first functional group of a first protomer with a second functional group of a copolymer molecule and a bond-forming reaction of a third functional group of a second protomer with a fourth functional group of said copolymer molecule.

126. (Original) The process of claim 123, wherein said copolymer is monofunctional, having only one functional group.

127. (Original) The process of claim 123, wherein said copolymer is monofunctional, having at least two functional groups.

128. (Original) The process of claim 123, wherein said condensing is performed at a temperature of lower than about 180°C.

129. (Original) The process of claim 123, wherein said condensing is performed at a temperature of lower than about 150°C.

130. (Original) The process of claim 123, wherein said condensing is performed in the presence of a catalyst.

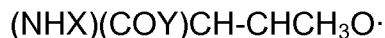
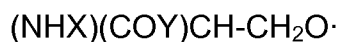
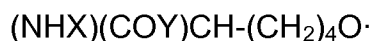
131. (Original) A polymer made according to the process of claim 114.

132. (Previously Presented) A polymer comprising at least one bond A-B, wherein

A is selected from the group of radicals consisting of:

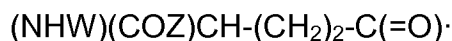
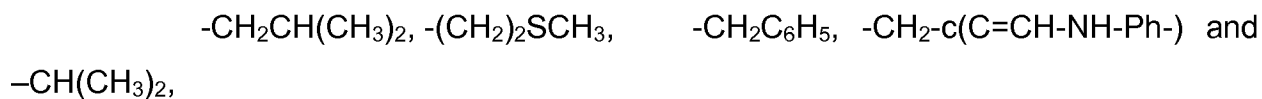
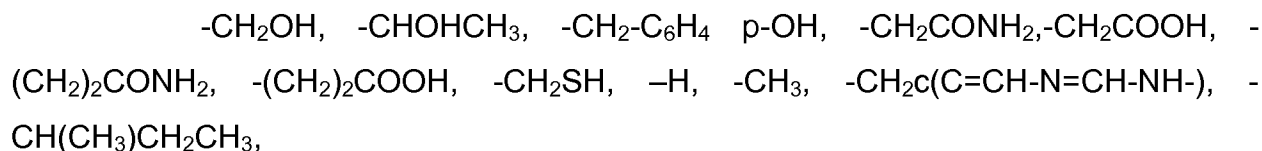
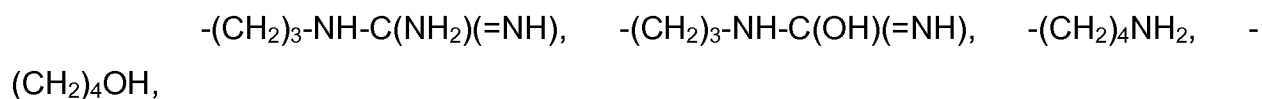


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and

B is selected from the group of radicals consisting of

wherein R_B is selected from the group consisting of:

wherein Y and Z are independently selected from the group consisting of OH and a proteinaceous material; and

wherein W and X, are independently selected from the group consisting of H and a proteinaceous material; and

wherein bond A-B is an ester bond.

133. (Original) The polymer of claim 132 comprising at least two bonds A-B.

134. (Original) The polymer of claim 132 comprising at least five bonds A-B.

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135. (Original) The polymer of claim 132, wherein:
A is a $(\text{NHX})(\text{COY})\text{CH}-(\text{CH}_2)_3\text{-NH-C(=NH)O}\cdot$ radical; and
B is a $(\text{NHW})(\text{COZ})\text{CH-CH}_2\text{-C(=O)}\cdot$ radical.
136. (Original) The polymer of claim 132, wherein:
A is a $(\text{NHX})(\text{COY})\text{CH}-(\text{CH}_2)_4\text{O}\cdot$ radical; and
B is a $(\text{NHW})(\text{COZ})\text{CH-CH}_2\text{-C(=O)}\cdot$ radical.
137. (Original) The polymer of claim 132, wherein:
A is a $(\text{NHX})(\text{COY})\text{CH-CH}_2\text{O}\cdot$ radical; and
B is a $(\text{NHW})(\text{COZ})\text{CH-CH}_2\text{-C(=O)}\cdot$ radical.
138. (Original) The polymer of claim 132, wherein:
A is a $(\text{NHX})(\text{COY})\text{CH-CHCH}_3\text{O}\cdot$ radical; and
B is a $(\text{NHW})(\text{COZ})\text{CH-CH}_2\text{-C(=O)}\cdot$ radical.
139. (Original) The polymer of claim 132, wherein:
A is a $(\text{NHX})(\text{COY})\text{CH-CH}_2\text{-C}_6\text{H}_4\text{ p-O}\cdot$ radical; and
B is a $(\text{NHW})(\text{COZ})\text{CH-CH}_2\text{-C(=O)}\cdot$ radical.
140. (Canceled)
141. (Original) The polymer of claim 132, wherein:
A is a $(\text{NHX})(\text{COY})\text{CH}-(\text{CH}_2)_3\text{-NH-C(=NH)O}\cdot$ radical; and
B is a $(\text{NHW})(\text{COZ})\text{CH}-(\text{CH}_2)_2\text{-C(=O)}\cdot$ radical.
142. (Original) The polymer of claim 132, wherein:
A is a $(\text{NHX})(\text{COY})\text{CH}-(\text{CH}_2)_4\text{O}\cdot$ radical; and
B is a $(\text{NHW})(\text{COZ})\text{CH}-(\text{CH}_2)_2\text{-C(=O)}\cdot$ radical.

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143. (Original) The polymer of claim 132, wherein:

A is a $(\text{NHX})(\text{COY})\text{CH}-\text{CH}_2\text{O}\cdot$ radical; and

B is a $(\text{NHW})(\text{COZ})\text{CH}-(\text{CH}_2)_2-\text{C}(=\text{O})\cdot$ radical.

144-153. (Canceled)

REASONS for ALLOWANCE

The following is an examiner's statement of reasons for allowance:

1. Upon further consideration Examiner agreed with Applicant that prior art of record, specifically reference to Goodman (RE. 30,170) alone or in combination with of Gouesnard " Reactivite du nitrite de sodium. V. Action sur les amino-acides, peptides et proteines" *BULLETIN DE LA SOCIETE CHIMIQUE DE FRANCE* 1989 N° does not render Applicant's claimed subject matter obvious to one of ordinary skill in the art.

It is noted, that Goodman does not disclose process for obtaining polymer, comprising amino acids and hydroxyamino acids as it required by limitations of Applicant's claims 132-139 and 141-143, but rather excluding multifunctional acids as hydroxyamino acids from process of preparing polyesters, comprising amino acids and hydroxyacids in view of multiple reactions involving amino, hydroxyl and carboxyl groups. In addition note, that Gouesnard does provide method of obtaining hydroxyamino acids fro protein sources, but does not provide teaching or suggestion for

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incorporating hydroxyamino acids to polyester, comprising residue of natural amino acids and residue of hydroxyamino acids connected by ester bond.

2. Regarding to International Search Report dated April 2, 2009 cited by Applicant (see IDS dated June 2, 2009) note, that reference to Shukla et al." Zein: the industrial protein from corn" discloses presence of amino acids and hydroxyamino acids in zein. However, zein as a natural protein, comprises different amino acids connected to each other by peptide bond, and for this reason different from Applicant's claimed polymeric structure, which requires presence of ester bond (see claims 114, 123 and 132 above).

3. For reasons above, subject matter claimed by Applicant in Claims 114 - 139 and 141-143 are deemed to be allowable over prior art of record.

4. Claims 132 -139 and 141- 143 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 114 - 131 directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104 and found to be allowable.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on August 21, 2007 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over

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the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GENNADIY MESH whose telephone number is (571)272-2901. The examiner can normally be reached on 10 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272 1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gennadiy Mesh

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Examiner
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/GM/

/Vasu Jagannathan/
Supervisory Patent Examiner, Art Unit 1796